King, Valerie A.

From: Zedler, Barbara

Sent: Friday, October 03, 2003 6:12 PM

To: Adams, Candace R.; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans; Sarkar, Mohamadi; Unverdorben, Martin; Wang, Jingzhu

Subject: standards for clin R&D studies re protocols, SAPs, CSRs

Sensitivity: Confidential

Folks,

The attached is the current consensus document for PMUSA clinical R&D studies. Pls review it carefully and use it as a framework in drafting SAPs and CSRs in particular. I have also sent this to MDS for guidance. It is a LIVING document, however, that will be revised, updated, expanded (and maybe contracted) as time, experience and learnings evolve. Pls let me know if you have any suggestions or comments now or going forward. Thanks for all your great work!

P.S. We will also be issuing a standardized CSR Vol. 1 TOC for exposure studies based on ICH Guidelines, and lists of standard definitions, abbreviations and calculations.

Barb

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